

## CLAIMS

The following listing of claims replaces all prior versions of claims in the application.

### Listing of claims

1-36. (Cancelled)

37. (Currently Amended) A method of treating or managing cancer in a patient in need thereof comprising: administering to a the patient a pharmaceutical composition ~~with an effective amount of~~ comprising about  $0.5 \times 10^9$  to  $1 \times 10^{10}$  heat inactivated killed *mycobacterium w*, wherein cancer in the patient is a primary cancer or a secondary (metastatic) lesion thereof selected from the group consisting of multiple myeloma, breast cancer, esophageal cancer, bladder cancer, non small cell lung carcinoma, head and neck cancer, pancreatic cancer, a cancer that metastasizes to bone, liver, or lung, or combinations thereof.

38. (Currently amended) The method of claim 37, wherein the method ~~is for decreasing the burden of cancer tissue~~ provides symptomatic relief from one or more of pain, decreased hemoglobin, cough, breathlessness, dysphagia, neutropenia or irregular sleep in the patient suffering from cancer.

39. (Previously Presented) The method of claim 37, wherein the method is for increasing efficacy of radiotherapy or chemotherapy in the treatment of cancer.

40. (Currently amended) The method of claim 37, wherein the method is for ~~the~~ reducing side effect of the radiotherapy or chemotherapy.

41. (Previously Presented) The method of claim 40, wherein the side effects are hematological side effects.

42. (Currently amended) The method of claim 40, wherein the side effects are reduced to avoid interruption of chemotherapy.

43. (Previously Presented) The method of claim 40, wherein the side effects are leucopenia, thrombocytopenia, anaemia, nausea, vomiting or mucositis.

44-46 (Cancelled)

47. (Currently amended) The method of claim 37, wherein the heat for inactivating killing is applied by means of autoclaving.
- 48-51. (Cancelled)
52. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises one or more adjuvants.
53. (Previously Presented) The method of claim 52, wherein the pharmaceutical composition further comprises a surfactant.
54. (Previously Presented) The method of claim 53, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate.
55. (Previously Presented) The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.4% by weight/volume of the pharmaceutical composition.
56. (Previously Presented) The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.1% by weight/volume of the pharmaceutical composition.
57. (Currently amended) The method of claim 37, wherein the *Mycobacterium w* is urease negative, or dose not hydrolyze polyoxyethylene (20) sorbitan monooleate, or does not produce niacin, and provides a strong positive response to nitrate reduction tests.
58. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered alone or in combination with other modes of therapy selected from radiotherapy and chemotherapy.
59. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by parenteral route.
60. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition is administered by intramuscular, subcutaneous, or intradermal route.

61-62 (Cancelled)

63. (Currently amended) The method of claim 37, wherein the effective amount of pharmaceutical composition is in a unit dosage form comprising from about  $[[10^8]]$   $10^9$  to  $10^{10}$  *Mycobacterium w*.

64. (Previously Presented) The method of claim 37, wherein the pharmaceutical composition further comprises a preservative.

65. (Cancelled)

66. (Currently Amended) A method of improving the quality of life in a patient suffering from cancer comprising administering to [[a]] the patient a pharmaceutical composition with an effective amount of a therapeutic agent selected from the group consisting of a) heat killed whole cell comprising about  $0.5 \times 10^9$  to  $1 \times 10^{10}$  heat inactivated mycobacterium w, and b) an enzymatic extraction of Mycobacterium w, wherein the enzyme is selected from the group consisting of litiase and pronase wherein cancer in the patient is a primary cancer or a secondary (metastatic) lesion thereof selected from one or more of multiple myeloma, breast cancer, esophageal cancer, bladder cancer, non small cell lung carcinoma, head and neck cancer, pancreatic cancer, or a cancer that metastasizes to bone, liver, or lung.

67. (Previously Presented) The method of claim 66, wherein the improvement in quality of life is obtained in the absence of other modes of treatment.

68. (Previously Presented) The method of claim 66, wherein the improvement in quality of life is obtained with addition of other modes of treatment selected from radiotherapy and chemotherapy.

69. (Currently Amended) A method of amelioration of symptoms associated with cancer in a patient in need thereof comprising: administering to [[a]] the patient with an effective amount of therapeutic agent selected from the group consisting of a) heat killed whole cell a pharmaceutical composition comprising heat inactivated mycobacterium w, and b) an enzymatic extraction of Mycobacterium w, wherein the enzyme is selected from the group consisting of litiase and pronase wherein the symptoms associated with cancer is selected from the group

consisting of pain, decreased hemoglobin, cough, breathlessness, dysphagia, neutropenia and irregular sleep, or combinations thereof.

70. (Previously presented) The method of treating cancer according to claims 37, wherein the pharmaceutical composition is administered intradermally.

71. (Previously presented) The method of treating cancer according to claims 37, wherein the cancer is superficial bladder cancer and the composition is administered intradermally over the deltoid region.

72. (Previously presented) The method of treating cancer according to claims 37, wherein the cancer is muscle invasive bladder cancer and the composition is administered intradermally over the deltoid region.

73. (New) The method of treating cancer according to claim 66, wherein the pharmaceutical composition is administered intradermally.

74. (New) The method of treating cancer according to claim 66, wherein the cancer is superficial bladder cancer and the composition is administered intradermally over the deltoid region.

75. (New) The method of treating cancer according to claim 66, wherein the cancer is muscle invasive bladder cancer and the composition is administered intradermally over the deltoid region.